



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-D-0868]

### Development and Submission of Near Infrared Analytical Procedures; Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, Health and Human Services (HHS).

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Development and Submission of Near Infrared Analytical Procedures." This guidance provides recommendations to applicants to aid the development, validation, and use of near infrared (NIR)-based analytical procedures in evaluating the identity, strength, quality, purity, and potency of drug substances and drug products. The recommendations apply to new drug applications (NDAs), abbreviated new drug applications (ANDAs), and supplemental NDAs and ANDAs for small molecule drugs. The principles in this guidance also apply to drug substances and drug products covered in Type II drug master files. This guidance finalizes the draft guidance of the same title issued on March 31, 2015.

**DATES:** The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances at any time as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to

<https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2015-D-0868 for "Development and Submission of Near Infrared Analytical Procedures." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper

submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Eugenia Nashed, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4154, Silver Spring, MD 20993-0002, 301-796-1723.

**SUPPLEMENTARY INFORMATION:**

I. Background

FDA is announcing the availability of a guidance for industry entitled "Development and Submission of Near Infrared Analytical Procedures." This guidance provides recommendations to applicants to aid the development, validation, and use of NIR-based analytical procedures in evaluating the identity, strength, quality, purity, and potency of drug substances and drug products. The recommendations apply to NDAs, ANDAs, and supplemental NDAs and ANDAs for small molecule drugs. The principles in this guidance also apply to drug substances and drug products covered in Type II drug master files. FDA intends to issue recommendations specific to NIR methods used for biological products under biologics license applications in a future revision to this guidance. Specifically, this guidance, among other things, (1) addresses the development and submission of NIR analytical procedures used during and for the manufacture and analysis of pharmaceuticals (including raw materials, in-process materials and intermediates, drug substances, and finished products); (2) provides recommendations to manufacturers for applying the concepts described in the guidance for industry entitled "PAT--A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance" (<https://www.fda.gov/media/71012/download>) and the International Council for Harmonisation guidance for industry entitled "Q2(R1) Validation of Analytical Procedures: Text and Methodology" (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q2-r1-validation-analytical-procedures-text-and-methodology>) to NIR analytical procedures that use chemometric models; and (3) describes the type of information that should be submitted about NIR analytical procedures in applications.

This guidance pertains only to the development and validation of NIR analytical procedures and does not provide recommendations concerning the setup, qualification, maintenance, or calibration of NIR instruments. Although this guidance specifically addresses NIR spectroscopy, this guidance's concepts of validation can be applied to other multivariate analytical techniques, including, for example, Raman.

This guidance finalizes the draft guidance entitled "Development and Submission of Near Infrared Analytical Procedures" issued on March 31, 2015 (80 FR 17057). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include updates to reflect Agency regulatory experience and technological advancements in the industry, as well as management of NIR procedures over the life cycle of the products.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the development and submission of NIR analytical procedures. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 for NDAs and in 21 CFR parts 314 and 601 for annual reports, ANDAs, and supplements to applications have been approved under OMB control numbers 0910-0001 and 0910-0338, respectively. The collections of information in 21 CFR part 211 for current good manufacturing practices for

finished pharmaceuticals and medical gases have been approved under OMB control number 0910-0139.

### III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs> or <https://www.regulations.gov>.

Dated: August 2, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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